A bill for an act

relating to health; preventing conflicts of interest; banning gifts from drug or medical device manufacturers or distributors to physicians and formulary committee members; amending Minnesota Statutes 2008, sections 151.461; 151.47, subdivision 1; 256B.0625, subdivision 13c; proposing coding for new law in Minnesota Statutes, chapter 62J.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[62J.241] DISCLOSURE OF PAYMENTS TO PRACTITIONERS.**

Subdivision 1. **Disclosure required.** Each pharmaceutical manufacturer, wholesale drug distributor, or medical device manufacturer or their agent shall file with the commissioner of health an annual report that identifies all payments, honoraria, reimbursement, or other compensation paid to practitioners or to sponsors of a medical conference, professional meeting, or other educational program during the preceding calendar year.

Subd. 2. **Report format.** The format of the report shall be standardized and shall include at a minimum the nature and value of any payment to a particular practitioner or sponsor during the year and shall identify the practitioner or the sponsor. Reports filed under this provision are public data and must be made available on the department Web site in an easily accessible and searchable format.

Sec. 2. Minnesota Statutes 2008, section 151.461, is amended to read:

151.461 GIFTS TO PRACTITIONERS PROHIBITED.

Subdivision 1. **Prohibition.** It is unlawful for any pharmaceutical manufacturer ~~or,~~ wholesale drug distributor, or medical device manufacturer or distributor, or any agent thereof, to offer or give any gift ~~of value~~ or to request another person to give a gift to a

practitioner. ~~A medical device manufacturer that distributes drugs as an incidental part of its device business shall not be considered a manufacturer, a wholesale drug distributor, or agent under this section.~~ A practitioner may not accept a gift from a manufacturer or distributor or from an agent of either.

Subd. 2. **Definition of gift.** For purposes of this section, "gift" has the meaning given under section 10A.071.

Subd. 3. **Exceptions.** ~~As used in this section, "gift" does not include~~ The prohibition in this section does not apply to:

(1) professional samples of a drug provided to a ~~prescriber~~ practitioner for free distribution to uninsured or low-income patients, if there is evidence-based medicine to support the clear superiority of the drug over less costly alternatives available;

~~(2) items with a total combined retail value, in any calendar year, of not more than $50;~~

~~(3) a payment~~ (2) an unrestricted grant to the sponsor of a medical conference, professional meeting, or other educational program, provided that the grantor has no influence on the content, presenters, or attendees at the event and provided the payment is ~~not made directly to a practitioner and is used~~ solely for bona fide educational purposes; is made to underwrite the conference, meeting, or program; is not meant to subsidize any particular attendees; and is not tied to the attendance of any particular practitioner;

~~(4)~~ (3) reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting if the honoraria for the speech or presentation does not exceed the standard hourly billing rate of the practitioner;

~~(5)~~ (4) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project that has the potential of advancing medical care or establishing an improved understanding of the safety, performance, or improvement in clinical outcomes of a drug or medical device. The compensation for these services must not exceed the standard hourly billing rate of the practitioner;

~~(6)~~ (5) informational publications and educational materials, provided that the materials were produced and published by the drug manufacturer or medical device manufacturer; ~~or~~

~~(7)~~ (6) salaries or other benefits paid to employees. If a practitioner who is currently practicing in Minnesota is also an employee or agent of a drug manufacturer, wholesale drug distributor, or medical device manufacturer or distributor, the practitioner must report the source, the amount, and the nature of the compensation received to the Board

of Medical Practice, and must notify a patient of the employment relationship before prescribing or recommending any medication or medical device from that manufacturer or distributor to the patient;

(7) bona fide training or educational programs conducted or sponsored by a medical device manufacturer or distributor for the sole purpose of training the practitioner in the use of a medical device and any reasonable expenses associated with attending the training or educational program; or

(8) reasonable payment to the practitioner for intellectual property or patent royalties on a medical device provided that the practitioner is named on the patent.

Subd. 4. **Report.** (a) When a practitioner receives compensation under subdivision 3, clause (3), (4), or (8), the source, the amount, and the nature of the compensation must be reported to the Board of Medical Practice, and the practitioner must notify a patient of the existence of a financial relationship before prescribing any medication or device from that manufacturer or distributor to the patient.

(b) For purposes of this section, "practitioner" includes the employees of the clinic or facility where the practitioner is practicing and includes family members of the practitioner.

Sec. 3. Minnesota Statutes 2008, section 151.47, subdivision 1, is amended to read:

Subdivision 1. **Requirements.** All wholesale drug distributors are subject to the requirements in paragraphs (a) to (f).

(a) No person or distribution outlet shall act as a wholesale drug distributor without first obtaining a license from the board and paying the required fee.

(b) No license shall be issued or renewed for a wholesale drug distributor to operate unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board.

(c) The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within the state, or for a parent entity with divisions, subsidiaries, or affiliate companies within the state, when operations are conducted at more than one location and joint ownership and control exists among all the entities.

(d) As a condition for receiving and retaining a wholesale drug distributor license issued under sections 151.42 to 151.51, an applicant shall satisfy the board that it has and will continuously maintain:

(1) adequate storage conditions and facilities;

(2) minimum liability and other insurance as may be required under any applicable federal or state law;

(3) a viable security system that includes an after hours central alarm, or comparable entry detection capability; restricted access to the premises; comprehensive employment applicant screening; and safeguards against all forms of employee theft;

(4) a system of records describing all wholesale drug distributor activities set forth in section 151.44 for at least the most recent two-year period, which shall be reasonably accessible as defined by board regulations in any inspection authorized by the board;

(5) principals and persons, including officers, directors, primary shareholders, and key management executives, who must at all times demonstrate and maintain their capability of conducting business in conformity with sound financial practices as well as state and federal law;

(6) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, about each wholesale drug distributor to be licensed, including all pertinent corporate licensee information, if applicable, or other ownership, principal, key personnel, and facilities information found to be necessary by the board;

(7) written policies and procedures that assure reasonable wholesale drug distributor preparation for, protection against, and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or product shipping and receiving, outdated product or other unauthorized product control, appropriate disposition of returned goods, and product recalls;

(8) sufficient inspection procedures for all incoming and outgoing product shipments; and

(9) operations in compliance with all federal requirements applicable to wholesale drug distribution.

(e) An agent or employee of any licensed wholesale drug distributor need not seek licensure under this section.

~~(f) A wholesale drug distributor shall file with the board an annual report, in a form and on the date prescribed by the board, identifying all payments, honoraria, reimbursement or other compensation authorized under section 151.461, clauses (3) to (5), paid to practitioners in Minnesota during the preceding calendar year. The report shall identify the nature and value of any payments totaling $100 or more, to a particular practitioner during the year, and shall identify the practitioner. Reports filed under this provision are public data.~~

Sec. 4. Minnesota Statutes 2008, section 256B.0625, subdivision 13c, is amended to read:

Subd. 13c. **Formulary committee.** (a) The commissioner, after receiving recommendations from professional medical associations and professional pharmacy associations, and consumer groups shall designate a Formulary Committee to carry out duties as described in subdivisions 13 to 13g. The Formulary Committee shall be comprised of four licensed physicians actively engaged in the practice of medicine in Minnesota one of whom must be actively engaged in the treatment of persons with mental illness; at least three licensed pharmacists actively engaged in the practice of pharmacy in Minnesota; and one consumer representative; the remainder to be made up of health care professionals who are licensed in their field and have recognized knowledge in the clinically appropriate prescribing, dispensing, and monitoring of covered outpatient drugs. Members of the Formulary Committee shall not be employed by the Department of Human Services, but the committee shall be staffed by an employee of the department who shall serve as an ex officio, nonvoting member of the committee. The department's medical director shall also serve as an ex officio, nonvoting member for the committee. Committee members shall serve three-year terms and may be reappointed by the commissioner. The Formulary Committee shall meet at least quarterly. The commissioner may require more frequent Formulary Committee meetings as needed. An honorarium of $100 per meeting and reimbursement for mileage shall be paid to each committee member in attendance.

(b) A member of the formulary committee may not accept a gift or any professional samples from a drug manufacturer or wholesale drug distributor. A member of the formulary committee may not be an employee or an agent of a drug manufacturer or wholesale drug distributor.